

Applicants' Response

Claims 1-35 were rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-30 and 43-48 of prior U.S. Patent No. 6,801,805 (double patenting rejection).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by cancelling or amending the conflicting claims so they are no longer coextensive in scope. Applicants have cancelled claims 1-35 as originally submitted and have submitted new claims 36-46 for review.

Applicants point out new claims 36-46 are very similar to those claims previously prosecuted and issued in the companion application 09/514,907 (now U.S. Patent 6,567,705); however with the following notable changes. First, the claims have been directed to an implantable system for delivering a predetermined genetic material or protein to a selected location of a patient's heart. In addition, Applicants' have removed the requirement for a sensor in the system (which now appears as a dependent claim 59).

Removal of the prior double patenting rejection over U.S. Patent 6,801,805 and examination of the new claims 36-46 is respectfully requested.

Respectfully submitted,


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PENDING CLAIMS AS AMENDED
(MARKED UP VERSION)

1. (canceled) A delivery system for delivering a therapeutically effective amount of a predetermined genetic material to myocardial cells of a chosen location of a patient's heart, said genetic material being selected for the function of increasing the amplitude of the patient's cardiac signal so that it can be better sensed by an electrode, comprising:
 - a supply of said genetic material;
 - reservoir means for containing said genetic material; and
 - delivery means for delivering said genetic material from said reservoir to said myocardial cells, thereby increasing the amplitude of the cardiac signal and improving the signal to noise ratio that can be sensed by a pacemaker.
2. (canceled) The delivery system of claim 1, wherein said supply of genetic material comprises a bolus of ion channel protein selected for the function of increasing the amplitude of the cardiac signal..
3. (canceled) The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal end portion, and said reservoir means is located in said distal end portion.
4. (canceled) The delivery system of claim 3, wherein said distal end portion comprises a hollow helical element forming an interior, and said reservoir means comprises said interior with said supply therein.
5. (canceled) The delivery system of claim 1, wherein said delivery means comprises a catheter with a lumen for delivering said genetic material therethrough, said catheter having a distal tip communicating with said lumen for contacting said plurality of cells in the proximity of said electrode with said genetic material.
6. (canceled) The delivery system of claim 5, wherein said distal tip is a hollow helical needle tip.

7. (canceled) The delivery system of claim 5, wherein said catheter is a transvenous endocardial catheter.

8. (canceled) The delivery system of claim 1, wherein said reservoir contains a supply of 0.1-10 ml of said genetic material.

9. (canceled) The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal portion and an end tip, and wherein said reservoir means is contained in said distal portion, and further comprising force means for forcing said genetic material from said reservoir means and out of said end tip.

10. (canceled) The delivery system of claim 9, wherein said force means comprises a stylet.

11. (canceled) The delivery system of claim 1, wherein said delivery system comprises a hollow helical screw-in element loaded with a bolus of said genetic material.

12. (canceled) The delivery system of claim 11, wherein said element comprises ports for egress of said genetic material into said identified cardiac location when said element is screwed into said location, and further comprising soluble plugs in said ports to maintain them normally closed but which dissolve when said element is positioned within said patient's heart.

13. (canceled) The delivery system of claim 1, wherein said predetermined genetic material is DNA or RNA, and imparts chronic change in ion channel expression in said cardiac cells.

14. (canceled) The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal end portion, and said reservoir means is located in said distal end portion.

15. (canceled) The delivery system of claim 13, wherein said DNA or RNA encodes an ion channel protein.

16. (canceled) The delivery system of claim 15, wherein said ion channel protein is a sodium channel protein.

17. (canceled) The delivery system of claim 16, wherein said sodium channel protein is hH1.

18. (canceled) The delivery system of claim 1, wherein said predetermined genetic material is protein, and imparts acute change in sodium channel expression in said cardiac cells.

19. (canceled) The delivery system of claim 18, wherein said protein is an ion channel protein.

20. (canceled) The delivery system of claim 19, wherein said ion channel protein is a sodium channel protein.

21. (canceled) The delivery system of claim 20, wherein said sodium channel protein is hH1.

22. (canceled) An implantable delivery system for delivering doses of a therapeutically effective amount of a predetermined genetic material to myocardial cells in a chosen location of a patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in the myocardial cells to which it is delivered;

a catheter, said catheter having a distal tip portion for engaging the cells of said chosen location and delivering thereto said genetic material;

reservoir means for holding said supply of genetic material and providing it to said distal tip portion of said catheter; and

delivery means for delivering a therapeutically effective amount of said genetic material from said reservoir means through said distal tip portion to said chosen location.

23. (canceled) The system as described in claim 20, further comprising: control means for controlling operation of said delivery means to deliver respective said doses.

24. (canceled) The implantable delivery system of claim 23, wherein said control means comprises initiating means for initiating delivery of said genetic material, said initiating means comprising an external programmer.

25. (canceled) The implantable delivery system of claim 23, wherein said control means comprises automatic means for automatically initiating delivery of said genetic material.

26. (canceled) An implantable delivery system for delivering predetermined genetic material to cardiac cells adjacent to a pacing electrode positioned against the inner wall of a patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in cardiac cells to which it is delivered;

a catheter, said catheter having a distal tip portion for engaging said cardiac cells and delivering thereto said genetic material;

reservoir means for holding said supply of genetic material and providing it to said distal tip portion of said catheter; and

delivery means for delivering a therapeutically effective amount of said genetic material from said reservoir means through said distal tip portion to said cardiac cells.

27. (canceled) The implantable delivery system of claim 26, wherein the distal end of said distal tip portion further comprises a pacing electrode.

28. (canceled) The system as described in claim 26, further comprising:

control means for controlling operation of said delivery means to deliver respective said doses.

29. (canceled) The implantable delivery system of claim 26, wherein said control means comprises initiating means for initiating delivery of said genetic material, said initiating means comprising an external programmer.

30. (canceled) The implantable delivery system of claim 26, wherein said control means comprises automatic means for automatically initiating delivery of said genetic material.

31. (canceled) An implantable system for pacing a patient's heart and for delivering a predetermined genetic material to cardiac cells adjacent to a pacing electrode positioned in said patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in cardiac cells to which it is delivered;

a catheter, said catheter having proximal and distal ends, a lumen through at least a part thereof and connecting to said distal end, a pacing electrode positioned at said distal end for engaging said patient's heart wall, said electrode having a channel therethrough in communication with said lumen, and a conductor connecting said proximal end to said electrode,

a pulse generator connected electrically to said conductor at said catheter proximal end for delivering pace pulses to said electrode,

reservoir means for holding said supply of genetic material, and

delivery means for delivering said genetic material from said reservoir to said lumen, whereby said material passes through said lumen and said channel to said heart wall.

32. (canceled) The implantable system of claim 31, wherein said reservoir is mounted in said pulse generator.

33. (canceled) The implantable system of claim 31, wherein said delivery means is passive.

34. (canceled) The implantable system of claim 31, wherein said delivery means comprises a pump.

35. (canceled) The implantable system of claim 43, wherein said electrode is substantially concentric with respect to the catheter axis, and the channel passes through the center of said electrode.

36. (new) An implantable system for delivering a predetermined genetic material or protein to a selected location of a patient's heart, comprising an implantable delivery means for delivering a supply of said genetic material or protein to said selected location in said patient's heart wherein said genetic material is selected from the group consisting of DNA encoding an ion channel protein, RNA encoding an ion channel protein, and an ion channel protein.

37. (new) The implantable system of claim 1, wherein said implantable delivery means is implanted via a catheter.

38. (new) The implantable system of claim 1, wherein said catheter is an endocardial catheter.

39. (new) The implantable system of claim 2, wherein said delivery system further comprises a hollow helical screw-in element.

40. (new) The implantable system of claim 1, wherein said supply of genetic material is provided as a bolus to said selected location.

41. (new) The implantable system of claim 1, wherein said selected genetic material is a recombinant nucleic acid molecule encoding the ion channel protein.

42. (new) The implantable system of claim 8, wherein said ion channel protein is a sodium channel protein.

43. (new) The implantable system of claim 9, wherein sodium channel protein is hH1.

44. (new) The implantable system of claim 1, wherein the implantable delivery system improves the ability to sense the cardiac signal of said patient's heart.

45. (new) The implantable system of claim 1, wherein said genetic material or protein increases the amplitude of the cardiac signal of said patient's heart.

46. (new) An implantable system of claim 1, which includes an implantable pacing electrode for detecting cardiac signals.